

Serial No.: 10/579,090

Confirmation No.: 5257

Filed: April 11, 2007

For: DNA SEQUENCE AND EXPRESSED RECOMBINANT GLYCOPROTEINS RELATED TO FELINE THYROTROPIN

Remarks

The Office Action mailed 14 July 2009 has been received and reviewed. Claims 2, 3, 9, 34, 37, 63, 65, 70, 77-83, 85, 87, and 89-93 having been amended, claims 1, 4-8, 10-33, 39-59, 61, 62, 64, 66-69, 71-73, 75, 76, 84, 86, 94, and 95 having been canceled, without prejudice, the pending claims are claims 2, 3, 9, 34-38, 60, 63, 65, 70, 74, 77-83, 85, 87-93, and 96-98.

Reconsideration and withdrawal of the rejections are respectfully requested.

Applicants thank the Examiner for the rejoinder and examination of claims 9, 34, 36-38, 63, 65, 74, and 77-80.

Claims 2, 3, 34-36, 60, 70, 81-83, 85, 87, 88, 90-92, and 96-98 have been identified as allowable (page 17, Final Office Action mailed July 14, 2009). As recommended by the Examiner in the interview of September 2, 2009, allowed claim 2 has been amended to recite "consists of," rather than "consists essentially of," allowed claim 3 amended to depend from allowed claim 70, and allowed claim 70 to recite "an isolated feline thyrotropin β -subunit polypeptide." Allowed claims 34, 81-83, 85, 87, and 90-92 have been amended merely to add a dependency to an allowable claim. Applicants submit that such amendment adds no new matter and raises no new issues for examination. Applicants submit that as amended, claims 74, 77, 78, 79, and 80, all dependent from allowable claims and are allowable.

Claims 9, 63, 65, 74, 77, 78 have been "objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims" (page 17, Final Office Action mailed July 14, 2009). Applicants do not understand the inclusion of claim 74, dependent from allowed claim 70, in this objection. Applicants have amended claims 9, 63, 65, 77, and 78 to include all of the limitations of the base claims and any intervening claims, and submit that no new issues for examination are raised thereby and respectfully request the allowance of claims 9, 63, 65, 74, 77, and 78.

As recommended by the Examiner, claims 89 and 93 have been amended to clarify the claimed α -subunit polypeptide. Support for amended claims 89 and 93 is found, for example, in

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Example 9 (see, for example, pages 48-50), page 1, line 11, page 2, lines 21-22, and page 3, lines 7-13 of the specification. Applicants submit that no new issues for examination are raised by this amendment of claims 89 and 93, as the Applicant is following the guidance of the Examiner.

Examiner Interview

An Examiner Interview was held between Patent Examiner Zachary Howard, Primary Patent Examiner Bridget Brunner, and Applicants' Representative, Nancy Johnson, on September 2, 2009, in which proposed amendments in response to the Final Office Action mailed July 14, 2009, were discussed. Examiners Howard and Brunner are thanked for the courtesy of this interview.

In particular, Applicants thank Examiners Howard and Brunner for suggesting that the amendment of claim 89 to recite “a mammalian thyrotropin α -subunit polypeptide, wherein said thyrotropin α -subunit polypeptide binds the thyrotropin β -subunit polypeptide and forms a heterodimer that stimulates cells expressing thyroid stimulating hormone receptors (THS-R) to produce cAMP” and the amendment of claim 93 to recite “wherein the fusion protein further comprises a mammalian thyrotropin α -subunit polypeptide and wherein said fusion protein stimulates cells expressing thyroid stimulating hormone receptors (THS-R) to produce cAMP” would obviate the enablement and written description rejections of claims 89 and 93 under 35 U.S.C. §112, first paragraph.

Objection to Specification

The Examiner has objected to the specification, asserting that the recitation “The sequence showed 99% homology with tiger (*Panthera tigris*) common alpha subunit (Genbank accession number AF354939)” is improperly placed in Example 2 of the specification. Applicants continue to traverse this objection to the specification. However, to expedite prosecution, the specification has been amended to move this recitation to Example 1 (page 40, line 10 of the specification).

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The Examiner has also objected to the specification, asserting that statements made on page 40, lines 30-34 of the specification are inconsistent with statements made in Rayalam et al. (Domestic Animal Endocrinology 30:203-217, 2006). Applicant respectfully submit that it is inappropriate for the Examiner to request that the specification be edited in view of information that published after the filing date of the present application; doing so would potentially introduce new matter into the specification. Applicants continue to traverse this objection, however, to expedite prosecution, the specification has been amended to delete this recitation from the specification.

Applicants submit that these amendments to the specification add no new matter and raise no new issues for examination. The reconsideration and withdrawal of the objections to the specification is respectfully requested.

Objections to Claims

The Examiner has objected to claims 79, 89, and 93 because of a discrepancy in reciting “thyrotropin α subunit” without the use of a hyphen. Applicants submit that this objection is overcome in view of the amendment of claim 79 (removing this recitation) and claims 89 and 93 (to recite “thyrotropin α -subunit”). The reconsideration and withdrawal of this objection is respectfully requested.

The 35 U.S.C. §112, First Paragraph, Enablement Rejection

The Examiner has rejected claims 37, 38, 79, 80, 89, and 93 under 35 U.S.C. §112, first paragraph, alleging the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicants respectfully traverse this rejection.

Applicants submit that the inclusion of claims 37, 38, 79, and 80 in this rejection is moot in view of the amendment of these claims.

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As amended, claim 89 is drawn to “[t]he composition of claim 85 further comprising a mammalian thyrotropin α -subunit polypeptide, wherein said thyrotropin α -subunit polypeptide binds the thyrotropin β -subunit polypeptide and forms a heterodimer that stimulates cells expressing thyroid stimulating hormone receptors (THS-R) to produce cAMP” and claim 93 is drawn to “[t]he fusion protein of claim 93, wherein the fusion protein further comprises a mammalian thyrotropin α -subunit polypeptide and wherein said fusion protein stimulates cells expressing thyroid stimulating hormone receptors (THS-R) to produce cAMP.” Applicants respectfully submit that the specification enables the polypeptides of claims 89 and 93. See, for example, Example 9 (pages 48-50), page 1, line 11, page 2, lines 21-22, and page 3, lines 7-13 of the specification. The reconsideration and withdrawal of the enablement rejection of claims 37, 38, 79, 80, 89, and 93 under 35 U.S.C. §112, first paragraph, is respectfully requested.

The 35 U.S.C. §112, First Paragraph, Written Description Rejection

The Examiner has rejected claims 79, 80, 89, and 93 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserted that the specification does not provide adequate written description for the claimed thyrotropin α -subunits. Applicants respectfully disagree and traverse this rejection.

Applicants submit that the inclusion of claims 37, 38, 79, and 80 in this rejection is moot in view of the amendment of these claims.

As amended, claim 89 is drawn to “[t]he composition of claim 85 further comprising a mammalian thyrotropin α -subunit polypeptide, wherein said thyrotropin α -subunit polypeptide binds the thyrotropin β -subunit polypeptide and forms a heterodimer that stimulates cells expressing thyroid stimulating hormone receptors (THS-R) to produce cAMP” and claim 93 is drawn to “[t]he fusion protein of claim 93, wherein the fusion protein further comprises a mammalian thyrotropin α -subunit polypeptide and wherein said fusion protein stimulates cells expressing thyroid stimulating hormone receptors (THS-R) to produce cAMP.” Applicants respectfully submit that the specification, in view of what was known in the art, provides

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adequate written description for the claimed polypeptides of claims 89 and 93. See, for example, Example 9 (pages 48-50), page 1, line 11, page 2, lines 21-22, and page 3, lines 7-13 of the specification. The reconsideration and withdrawal of the written description rejection of claims 37, 38, 79, 80, 89, and 93 under 35 U.S.C. §112, first paragraph, is respectfully requested.

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Summary

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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CERTIFICATE UNDER 37 CFR §1.6:

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop AF, P.O. Box 1450, Alexandria, VA 22313-1450, on this 14 day of September, 2009.

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